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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/530,112	07/10/95	MATSUBARA	K 215/070

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EXAMINER

CAMPELL, B

ART UNIT	PAPER NUMBER
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1632

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DATE MAILED: 08/16/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

8/530,112

Applicant(s)

Matsubara et al

Examiner

Campbell

Group Art Unit

1632

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 5/7/99
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 3, 13, 21, 29-68 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3, 13, 21, 29-68 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The amendment filed May 7, 1999 has been entered.

The indicated allowability of claims 1, 3, 13 and 21 is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 1, 3, 13, 21 and 29-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See Interim guidelines for the requirement for Written Description as cited in the Federal Register, Vol. 63, No. 114, p. 3263.

Claims 1, 3, 13, 21 and 29-68 are directed to polynucleotides comprising one of the elected sequences. The claims encompass full-length cDNAs and possibly genomic sequences (depending on whether introns are present).

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In this case, the only species whose complete structures are disclosed are DNA molecules complementary to the disclosed sequences, or portions thereof. This is not representative of the full scope of the claimed genus as described above. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence). In this case, no other identifying characteristics of the claimed, but undisclosed, sequences are provided. Thus it is concluded that the written description requirement is not satisfied for all of the claimed genus.

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Enablement

Claims 1, 3, 13, 21 and 29-68 are rejected under 35 U.S.C. 112, first paragraph because the specification is enabling only for claims limited to polynucleotides consisting of the elected sequences, or fragments thereof.

The claims encompass polynucleotides comprising non-disclosed nucleic acid sequences attached to the disclosed SEQ ID Nos. When given their broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species including full-length cDNAs, genes, and protein coding regions. However, the specification fails to provide an enabling disclosure for what such polynucleotides would comprise and how one would use such polynucleotides. The instant specification is directed to the preparation and sequence characterization of particular polynucleotides that are disclosed. The polynucleotides represent fragments of cDNA clones prepared using the methods disclosed in the specification. However, these are the only polynucleotides that are disclosed. Further, the disclosed polynucleotides have not been characterized with regard to their particular function. For example, some cDNA clones could represent structural gene transcripts that would potentially encode proteins while others may represent transcribed pseudogenes or RNA molecules that have some undisclosed function within a cell. Moreover, the specification fails to disclose any protein sequences or functions for any proteins.

Finally, the full scope of the claims is not enabled because of the large number of sequences embraced by the claims coupled with the lack of adequate guidance in the application as to which sequences to isolate or construct. For example, since the instant application does not disclose the entire sequence of any particular gene corresponding to any one of the ten elected ESTs, and the instant application does not disclose or enable one of skill in the art to derive the complete cDNA and/or genomic DNA that corresponds to the gene from which any one of the ten elected ESTs is derived, one of skill in the art would need to perform undue experimentation to practice the full scope of the claims. The Court of Appeals for the Federal Circuit has ruled that claims that embrace a large number of species of polynucleotide sequences without proper guidance in the application as to how to make and use such

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polynucleotides do not meet the requirements of 35 U.S.C. § 112, first paragraph, *Amgen v. Chugai* (18 USPQ2d 1016 (Fed. Cir. 1991)).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be reached on Monday-Thursday from 8:00 to 4:30 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached on 703-308-2801. The FAX phone numbers for group 1600 are 703-308-4242 and 703-305-3014.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.



**BRUCE R. CAMPELL
PRIMARY EXAMINER
GROUP 1600**